



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Note to Reader
September 9, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

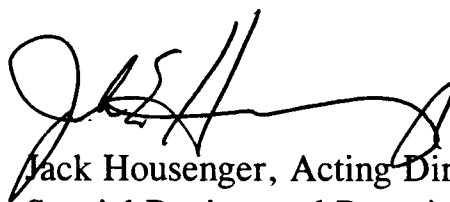
There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', with a long horizontal flourish extending to the right.

Jack Housenger, Acting Director
Special Review and Reregistration
Division



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Prevention, Pesticides, and Toxic Substances
Washington, DC 20460

May 14, 1998

MEMORANDUM

SUBJECT: Summary of EFED Concerns Regarding Fish Kill Incidents Attributed to Use of Profenofos on Cotton (**Profenofos** (List B; Case 2540; PC Code 111401))

TO: Kylie Rothwell, CRM
Betty Shackelford, Acting Branch Chief
Reregistration Branch III, SRRD (7508W)

FROM: ERB 4 Profenofos RED Task Team

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for
THROUGH: Mah Shamim, Branch Chief

Environmental Risk Branch 4, EFED (7507C)

MAY 22 1998

Novartis, the registrant for profenofos, provided comments to EFED's original (1996) risk assessment/ risk characterization chapter for the profenofos RED [Novartis, October 19, 1997, "Profenofos; Response to Draft RED Chapters from HED (6/18/96) and EFED (6/17/96)]. In evaluating these comments, we found numerous fish-kill incidents not reported in the original assessment that significantly affect our risk assessment. These incidents, reported in EFED's Ecological Incident Information System (EIIIS), include 15 fish kills attributed to profenofos between 1994 and 1996 (the only years currently listed in the database) in southern cotton-growing regions. In seven of the incidents, thousands of fish were killed per event, and in the other incidents more than 100 fish died in each event. The quality of the reported data is considered excellent and reliable. A table that provides details of the fish kills is attached to this memo.

The incidents indicate that, even when used according to label directions and under normal agricultural practices, profenofos can reach fish-bearing waters in sufficient concentrations to result in large fish kills. Fish-kill incidents occurred since the product labels were last revised, indicating that existing label recommendations are inadequate to protect aquatic organisms.

Upon discovery of these incidents, EFED notified SRRD that the aquatic risks in EFED's RED chapter were underestimates of the actual risks, and that EFED planned to revise

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the risk characterization to incorporate these incidents. On April 23 EFED scientists met with risk managers from SRRD and RD to discuss these issues. It was agreed at the meeting that EFED will provide SRRD with an explanation of our concerns regarding the fish kill incidents. This memo addresses these issues.

Analysis of Fish Kill Incidents

The EFED Ecological Incident Information System (EIIS) reports 15 fish-kill incidents attributed to profenofos during 1994 to 1996 (see table). These incidents occurred in the Deep South coastal cotton-growing region (1, 11, and 3 incidents in states of AL, LA, and MS, respectively). Aquatic habitats included lakes (seven incidents), creeks (four incidents), bayous (two incidents), and rivers (two incidents). The fish kills generally occurred from surface water runoff of profenofos, although spray drift during application also caused several hundred fish to die in one incident.

Seven incidents resulted in thousands (up to 150,000) of fish killed; eight incidents involved kills of more than 100 but less than 1000 fish. Fish species affected included buffalo, gar, shad, drum, carp, bowfin, bluegill, and channel catfish. In the majority of cases, at least water samples were taken and chemically analyzed for profenofos residue. In four incidents, fish tissue (e.g., liver, muscle) was also analyzed. In three reports, only profenofos residues were found from samples taken and were confirmed as the cause for a fish kill. One additional fish kill occurred after rainfall following the treatment of cotton fields with profenofos (no chemical analysis was conducted). In five other incidents, commonly used herbicide residues were detected along with profenofos but the latter was determined as the culprit. Methyl parathion residues were also found along with profenofos in three incidents and was also reported as a contributing factor in two incidents. On the other hand, azinphos-methyl and endosulfan were also detected along with profenofos in two separate incidents, and these two other insecticides were regarded as the major cause of the respective fish kills.

Frequent mass fish kills by profenofos are possible via surface water runoff, both in static (bayou and lake) and flowing (creek and river) water bodies based on these incident reports. Although measured residue levels were relatively low (below the fish LC_{50}), the initial profenofos concentrations at entry points probably are much higher considering the dilution factor of moving and big water bodies, as well as time of sampling (post incident). The quality of reports seems to be excellent because most incidents were investigated by a state agency (such as the Louisiana Department of Agriculture and Forestry) and chemically analyzed by the state university (such as Louisiana State University). In addition to water and sediment samples, fish tissue samples were sometimes analyzed.

The records indicate that the Curacron 8E product used at the times of these incidents had the label statement prohibiting aerial application "within 300 feet upwind of impounded water", and that label directions and precautions were followed by the certified applicators. That is, the incidents were not caused by misuse. EFED wants to stress that aerial spray drift buffer zones are ineffective with profenofos as the majority of the incidents were caused by surface runoff of the pesticide.

Comparison of Incidents to the 1996 Risk Assessment

The acute risk quotients in the 1996 RED chapter did not indicate that profenofos is a high risk to fish, and therefore we did not anticipate that such large numbers of fish could be killed by profenofos. The exposure values used in our risk quotients were based on data that do not adequately represent the concentrations of profenofos likely to be found in all fish-bearing waters. The environmental fate data provided by Novartis characterizes the fate of profenofos under alkaline conditions -- pH conditions which tend to favor more rapid degradation of profenofos. In the original RED chapter and risk characterization, EFED noted the existing data was inadequate to characterize the fate of profenofos under acidic to neutral conditions. Given that much of the cotton use area, particularly in the southeast U.S., contain soils which are acidic to neutral, this gap is significant and may underestimate persistence of profenofos and, thus, expected environmental concentrations (EECs). Therefore, the risk quotients would likely be substantially greater than those reported in the RED chapter, and more indicative of the actual risks as demonstrated by the fish kill incidents.

Regardless, the important issue is that valid and highly reliable field data indicate that the entry of profenofos into fish-bearing waters kills large numbers of fish when used according to label directions and under normal agricultural practices. The fact that fish-kill incidents occurred since the product labels were last revised indicates existing label recommendations are inadequate to protect aquatic organisms. EFED believes additional measures need to be explored to reduce the potential for future fish kills from profenofos use.

Fish Kill Incidents Involving Profenofos Reported in the EFED Ecological Incident Information System (EIIIS) From 1994 to 1996.

Case No/ Incident No.	Date	State/ County/ Water Body	Species	Reported Kill	Chemical Analysis (1)	Pesticide(s) Involved [Probability] (2)
96-68 I004021-004 I004668-006 I004875-006	8/6/96	LA/Richard Crew Lake	shad, carp, buffalo, bowfin	1200 - "extensive"	w, sm, sl	Profenofos: 0.62-1.08 ppb (w); 78.2- 363 ppb (sm); 100-1181 ppb (sl) [P] Methyl parathion: 0.21ppb (w) [UL] Atrazine, prometryn, cyanazine, norflurazon, metolachlor [UL]
96-69 I004021-005	8/6/96	LA/Richard La Fourche Lake	shad, buffalo	thousands	w	Profenofos: 0.7-1.05 ppb (w) [P] Atrazine, prometryn, cyanazine, norflurazon, metolachlor, clomazone [UL]
96-71 I004668-009 I004875-009	8/6/96	LA/Richard Cedar Lake in Delhi	shad, bowfin, bluegill	500	w	Profenofos: 0.16-0.68 ppb Cyanazine: 0.05-0.11 ppb Low dissolved oxygen
96-70 I004668-008 I004875-008	8/6/96	LA/Richard Boeuf River	shad, buffalo	200	w	Profenofos: 0.08-3.58 ppb [P] Atrazine: 1.18 ppb [UL] Cyanazine: 0.43-0.58 ppb [UL]
96-75 I004021-011 I004668-011	8/7/96	LA/Richard Dave's Bayou	buffalo, shad, gar	600	w	Azinphos-methyl: 2.63 ppb [P] Profenofos: 0.29 ppb [UL] Atrazine: 0.04 ppb [UL] Prometryn: 1.58 ppb [UL] Metolachlor: 0.01 ppb [UL]
I002211-003	7/28/94	MS/Humphreys Four Mile Lake	channel catfish, buffalo, bowfin, carp, gar	600	w	Profenofos: 0.71-0.38 ppb (w) only chemical detected
I002211-001	8/7/94	MS/Rankin Cane Creek	shad, catfish	3,000	w	Profenofos: 0.6-36.4 ppb (w) (8/12); 0.07-0.56 ppb (8/19) [P] Azinphos-methyl [UL]
I002211-002	8/14/94	MS/Warren Eagle Lake	buffalo, shad, bluegill, carp	650		Profenofos: [P] from drift

(1) Chemical Analysis: w = Water; t = Tissue; s = Sediment; f = Fish; sm = Shad muscle; sl = Shad Liver

(2) Probability of Causing Incident: HP = Highly Probable; P = Possible; UL = Unlikely

Fish Kill Incidents Involving Profenofos Reported in the EFED Ecological Incident Information System (EIIIS) From 1994 to 1996.

Case No/ Incident No.	Date	State/ County/ Water Body	Species	Reported Kill	Chemical Analysis (1)	Pesticide(s) Involved [Probability] (2)
6(A)(2) I002591-001	8/6/95	AL/Limestone Big Nance Creek	catfish, bluegill	240,000	w, t	Endosulfan>LC50 [HP] Profenofos<LC50 [UL] Heavy Rain
94-57 I001849-009	7/25/94	LA Crews Lake, Little Lake Lafourche, Lake Lafourche	shad, bowfin, buffalo, gar, drum, catfish	2,395	w, s, f	Profenofos [HP] Methyl parathion [HP]
96-74 I004668-010 I004875-010	8/8/96	LA/Madison Joe's Bayou	shad	200	w (4 da)	Profenofos: 0.23-1.19 ppb Atrazine: 0.59-0.79 ppb Cyanazine: 2.93-3.66 ppb
96-69 I004668-007 I004875-007	8/6/96	LA/Morehouse Little Lake Lafourche	shad, buffalo, bowfin	6,000	w	Profenofos: 0.75-1.5 ppb [HP] Atrazine: 0.43-2.35 ppb [UL] Cyanazine: 0.20-0.28 ppb [UL] Norflurazone: 0.20-0.77 ppb [UL]
94-54 I001849-007	7/20/94	LA/Richland Big Creek	fish	400	f	Profenofos [HP]
96-64 I004875-004 I004021-001 I004668-004	8/2/96	LA/Richland Boeuf River	shad, buffalo, gar	150,000	w, s, Liver	Profenofos:>0.28 ppm, liver [HP] Azinphos-methyl [UL] several pesticides in water, sediment [UL]
96-66 I004608-005 I004021-003 I004875-005	8/5/96	LA/Richard Big Creek	shad, buffalo, drum, gar	300	w	Profenofos: 1.1 ppb (bluegill LC50 0.019-0.3 ppb) [P -HP] Methyl parathion: 0.2 ppb (bluegill LC50 18 ppb) [P] Atrazine, prometryn, cyanazine, norflurazone, metolachlor [UL]